

## REMARKS/ARGUMENTS

These Remarks are responsive to the Office Action mailed September 9, 2007 ("Office Action"). Claims 1-43 are pending. Claims 1, 2, 4, 5, 8, 10, 12, 16, 18, 19, 23, 25, 29, 31, 34, 36, 39, and 41 have been amended. Support for the amended claims can be found in the originally filed claims and throughout the specification. For instance, support for the amended claims can be found at page 11, lines 15-21 of the originally filed application. Applicant respectfully requests allowance of the pending claims for the following reasons.

### Obviousness -- 35 U.S.C. § 103(a)

An invention is unpatentable under 35 U.S.C. § 103 for obviousness where "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a). "The ultimate issue of obviousness turns on four factual determinations: (1) the scope and content of the prior art, (2) the level of ordinary skill in the art, (3) the differences between the claimed invention and the prior art, and (4) objective indicia of nonobviousness." *Merck & Co. v. Teva Pharmaceuticals USA Inc.*, 73 USPQ2d 1641 (Fed. Cir. 2005) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966)). "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_, 82 USPQ2d 1385, 1396 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329 (Fed. Cir. 2006)).

The Office Action rejects the pending claims under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,004,573 ("Rathi").

Rathi discloses biodegradable low molecular weight triblock poly(lactide-co-glycolide) polyethylene glycol copolymers having reverse thermal gelation properties in aqueous solution at body temperature. The reverse thermal gelation property describes a compound that exists as a liquid solution at low temperatures and reversibly forms gels at physiologically relevant temperatures, to provide good drug release characteristics. Rathi, col. 4, ll. 56-61. The triblock copolymers of Rathi exist in the liquid state at low temperature, but upon injection into the body

form a gel depot from which the drugs are released at a controlled rate. Fig. 1 shows that the transition to gel states occurs at a temperature of approximately 20°C (for compositions having 10 wt. % copolymer) to approximately 12°C (for compositions having 28 wt. % copolymer). The weight average molecular weight of the triblock copolymers disclosed by Rath is between about 3100 and 4500 Daltons.

The claimed invention requires, among other features, a “polymeric composition [that,] when formed as an aqueous polymer solution, is a free flowing liquid at body temperatures.” However, Rath expressly discloses exactly the opposite—a polymer that becomes a gel at body temperature. The Office Action appears to be relying on some kind of inherency/obviousness theory to show that the composition of Rath is “a free flowing liquid at body temperature.” “In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” M.P.E.P. § 2112 (quoting *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original)). “The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic.” *Id.* (citing *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993)).

The Office Action bases its conclusion that the “free flowing liquid at body temperature” limitation is taught based on the misconception that “the polymer solution [of Rath] is flowable at body temperature.” Office Action, page 3. Specifically, the Office Action states at page 4 that:

Rath specifically discloses that the ABA-type block copolymer composition gels at body temperature, which is 37°C (abstract and column 1, lines 19-21) and this means that between 35 °C and 36.999 °C, the ABA-type polymeric composition of Rath is a liquid.

Initially, the examiner’s finding that Rath discloses a triblock copolymer solution is flowable at body temperature in accordance with the claims is clearly incorrect. Rath teaches that the polymer forms a gel depot at body temperature, which is not a flowable liquid as claimed. It appears that the examiner is stating that the liquid once injected is still a liquid while being exposed to body temperature. The claims, however, state flowable liquid at body temperature.

Even if the examiner were correct that the claims could be met by a polymer which transitions to a gel at exactly body temperature, the gels taught by Rath actually form a gel at a

temperature below body temperature, approximately 20°C or less as shown in Fig. 1. It is not surprising that the data in Rathí shows the sol-gel transition temperature being well below the body temperature over a range of possible aqueous compositions. Rathí discloses that a “drug is released at a controlled rate from the gel.” Rathí, Abstract. Were the polymer of Rathí a free flowing liquid upon injection, it would not function as a controlled release gel and the drug would exhibit a burst release profile which would make it unsuitable for its intended use in a controlled release system. *In re Gordon*, 221 USPQ 1125, 1127 (Fed. Cir. 1984) (“Indeed, in the French apparatus were turned upside down, it would be rendered inoperable for its intended purpose. . . . In effect, French teaches away from the board’s proposed modification.”). Accordingly, Rathí does not expressly teach a “polymeric composition [that,] when formed as an aqueous polymer solution, is a free flowing liquid at body temperatures.”

None of the compositions disclosed by Rathí inherently teach a “polymeric composition [that,] when formed as an aqueous polymer solution, is a free flowing liquid at body temperatures.” The Office Action at page 6 states that:

Thus, at those points when they are the same the polymeric compositions of the prior art and the invention are the same and thus the properties would be the same. Thus, the polymeric compositions of the invention and the prior art would have the same property. Specifically, the gellation properties of both composition would be the same and there is nothing in the instant claims that indicates that the properties are not.

Rathí discloses a number of examples, none of which meet the limitations of the claims. In fact, the molecular weight of the triblock copolymers of Rathí are all above the claimed range of 1500 to 3099, and every example of Rathí exhibits reverse thermal gellation upon exposure to body temperature. Thus, the Office Action’s conclusion that Rathí teaches a composition that is flowable at body temperature is completely without merit.

The Office Action further states at page 6 that:

It appears that there is an aspect of applicants’ invention that allows the composition to remain liquid at above body temperature and applicants have not communicated that in the claims.

Applicant is unaware of any legal basis for rejecting the claim based on issues “not communicated” in the claims. For instance, it is well established that “[a] claim is not fatally indefinite for failing specifically to delineate the point at which the change in physical

phenomenon occurs.” *Andrew Corp. v. Gabriel Electronics Inc.*, 6 USPQ2d 2010, 2014 (Fed. Cir. 1988). If the examiner continues to maintain this basis for rejecting the claims, Applicant requests clarification of the legal basis for the examiner’s position.

The claims require, among other limitations, a weight average molecular weight in the range of 1500 to 3099 Daltons, whereas Rathí discloses polymers having average molecular weights of about 3100 to 4999. The Office Action appears to base its inherency argument regarding the claimed requirement of “a free flowing liquid at body temperatures” at least in part on the closeness of the molecular weight ranges recited in the claims and those of Rathí. However, this analysis ignores the express teachings of Rathí that its compositions form a gel—not a free flowing liquid—at body temperature. The burden is on the examiner to establish that the polymer of Rathí is necessarily, i.e., *must* be, a free flowing liquid at body temperature, not that this characteristic “*may* occur.” See M.P.E.P. § 2112. Given that the compositions of Rathí form gels at approximately 20°C or less, they do not result in a free flowing liquid at body temperature. Accordingly, the claimed limitation of “said composition forms a free flowing liquid at body temperatures in an aqueous environment” is not disclosed by the cited reference.

For all the foregoing reasons, the rejection of the pending claims under 35 U.S.C. § 103(a) as being unpatentable over Rathí is improper and must be withdrawn.

#### **Obviousness-Type Double Patenting**

The Office Action rejects the pending claims for obviousness-type double patenting over U.S. Patent Nos. 6,592,899, 6,117,949, and 6,201,072. A terminal disclaimer is filed to overcome the obviousness-type double patenting rejection in view of U.S. Patent No. 6,592,899.

The Office Action fails to articulate a specific basis for finding obviousness-type double patenting in view of U.S. Patent Nos. 6,117,949 and 6,201,072. Applicant would point out that the ‘949 and ‘072 claim priority to Rathí discussed above. Applicant would point out that Rathí does not teach a composition that forms a free flowing liquid at body temperatures in an aqueous environment. Likewise, the claims of the ‘949 and ‘072 patents do not recite a composition that forms a free flowing liquid at body temperatures in an aqueous environment. For reasons discussed above, it would not have been obvious to a person having ordinary skill in the art at the time of the invention to modify the claimed invention of Rathí to specify a composition that forms a free flowing liquid at body temperatures in an aqueous environment. Accordingly, the

rejection of the pending claims for obviousness double patenting over U.S. Patent Nos. 6,592,899, 6,117,949, and 6,201,072 must be withdrawn.

**CONCLUSION**

In view of the above remarks, early notification of a favorable consideration is respectfully requested.

In the event of any variance between this amount and the fees determined by the U.S. Patent and Trademark Office, please charge or credit any such variance to the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,

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